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In the Supreme Court of the United States

OCTOBER TERM, 1997

TANABE SEIYAKU CO., ET AL., PETITIONERS

v.

INTERNATIONAL TRADE COMMISSION, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE FEDERAL RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

Whether the Court of Appeals for the Federal Circuit correctly applied the doctrine of equivalents, as refined by this Court in *Warner-Jenkinson Co.* v. *Hilton Davis Chemical Co.*, 117 S. Ct. 1040 (1997), to the facts of this case.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1-19) is reported at 109 F.3d 726. The public version of the opinion of the International Trade Commission (Pet. App. 22-32) and the initial determination of the administrative law judge (Pet. App. 33-250) are published in USITC Pub. No. 2902.

JURISDICTION

The judgment of the court of appeals was entered on March 7, 1997. A petition for rehearing was denied on June 6, 1997. Pet. App. 20-21. The petition for a writ

of certiorari was filed on September 4, 1997. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Petitioner Tanabe Seiyaku Co. ("Tanabe") holds a United States patent (the '035 patent) on an improved process to manufacture high yields of diltiazem hydrochloride, a pharmaceutical product used to treat cardiovascular disease. Pet. App. 4. Tanabe also held an earlier patent (the '257 patent), now expired, on diltiazem hydrochloride itself. *Ibid.*

Claim 1 of the '035 patent describes a method of producing a diltiazem precursor through a chemical reaction using particular bases with particular solvents. Pet. App. 4-5. The claim identifies five specific base/solvent combinations for use in that process: (1) potassium hydroxide with acetone, (2) potassium carbonate with acetone, (3) potassium carbonate with a lower alkyl acetate, (4) potassium carbonate with acetone and water, and (5) potassium carbonate with lower alkyl acetate and water. *Id.* at 5-6. The second combination—potassium carbonate and acetone—is of concern in this case.

2. On February 25, 1993, petitioners Tanabe and Marion Merrell Dow, Inc. filed a complaint with the International Trade Commission, alleging that certain corporations were violating Section 337 of the Tariff Act of 1930, 19 U.S.C. 1337, by importing diltiazem products manufactured by a process that infringed claim 1 of the '035 patent. Pet. App. 2.[1]

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[1] In pertinent part, Section 337 prohibits importing into the United States, selling for importation, and selling within the United States after importation articles that are made, produced, processed, or mined under, or by means of, a process

Among the corporations named in the complaint were respondents Orion Corporation Fermion, Copley Pharmaceuticals, Inc., Interchem Corporation, and Rhone-Poulenc Rorer, Inc. (collectively, Fermion). *Ibid.*

The accused Fermion process uses potassium carbonate with the solvent butanone, rather than acetone, as in claim 1 of the '035 patent. Pet. App. 6. It is undisputed that Fermion's potassium carbonate/butanone combination is not identical to any of Tanabe's claimed combinations and thus does not literally infringe claim 1. *Ibid.* Petitioners argued, however, that because acetone and butanone have similar chemical structures (*i.e.*, they are both ketones), they are interchangeable, and thus that Fermion's process infringes the '035 patent under the doctrine of equivalents. *Id.* at 6-7.

The Commission initiated its investigation of petitioners' complaint on March 31, 1993, and referred the matter to an administrative law judge for an evidentiary hearing and initial determination. Pet. App. 40-42.

3. On February 1, 1995, the ALJ issued his initial determination, which found no violation of Section 337. Pet. App. 22. The ALJ turned first to the scope and meaning of the patent claim at issue. *Id.* at 49-69. He noted that Tanabe had, from the outset of its prosecution of the '035 patent application in the Patent and Trademark Office, limited the scope of its claim to specific combinations of bases and solvents. *Id.* at 54, 56. In particular, Tanabe had named only a single ketone—acetone—in the claim, instead of naming broader categories of bases and solvents, as it had

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covered by the claims of a valid and enforceable U.S. patent. 19 U.S.C. 1337(a)(1)(B)(ii).

in its other patents. *Id.* at 54, 58. The ALJ concluded that a person "of ordinary skill in the art" would have read the '035 patent to indicate that acetone was the only ketone suitable for use in the claimed reaction. *Id.* at 59.

The ALJ also found that Tanabe had made statements during its prosecution of the patent to limit the scope of the claim. Pet. App. 54-55. Tanabe had distinguished its invention over the prior art (including its own '257 patent) by stating that its precise base/solvent combinations produced significantly higher yields of diltiazem than had previously been possible. *Ibid.* Base/solvent combinations that did not attain such high yields were not recited in the claim language or mentioned to the Patent and Trademark Office. Indeed, Tanabe scientists considered such combinations to be failures. *Id.* at 55. The ALJ thus found that a person of ordinary skill in the art would have read the '035 patent as claiming only a method of producing high yields of diltiazem using specific base/solvent combinations. *Id.* at 55, 56.

The ALJ further found that Tanabe's statements during its foreign prosecution of similar patent applications confirmed that only the five base/solvent combinations identified in the applications were understood to produce high yields of diltiazem. Pet. App. 59. In response to rejections from three foreign patent offices, Tanabe argued that its claimed process was patentable over the prior art, because the five base/solvent combinations produced significantly better results than other combinations, including combinations that contained either a base or a solvent, but not both, disclosed in the '035 patent. *Id.* at 60-62. The ALJ concluded that those statements, together with the '035 patent's narrow claim language, specification,

and prosecution history, indicated that "the '035 patent is an improvement patent based on precisely defined base/solvent combinations." *Id.* at 67-68.

The ALJ then turned to whether the Fermion process, while not the same as the process described in the '035 patent, nonetheless infringes that patent under the doctrine of equivalents. The ALJ noted that acetone and butanone, although chemically similar, are not identical and do not have the same chemical properties. Pet. App. 120. In fact, he observed that Fermion, Tanabe, and Tanabe's expert all had to engage in extensive testing and experimentation before they could produce high yields of diltiazem using butanone as a solvent. *Id.* at 118-119, 121-123. The ALJ found that butanone is not a simple substitute for acetone in the production of diltiazem, and that the differences between the Tanabe and Fermion processes were substantial. *Id.* at 121, 123-124. He thus found no infringement under the doctrine of equivalents.

The Commission affirmed the ALJ's construction of claim 1 and his finding of non-infringement under the doctrine of equivalents. Pet. App. 26-28.[2]

4. A unanimous panel of the Federal Circuit affirmed on March 7, 1997. Pet. App. 1-19. The court, like the ALJ and the Commission, began its analysis by construing the scope and meaning of Tanabe's claim. *Id.* at 12-14. The court recognized that such an inquiry requires consideration of the claim lan-

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[2] The ALJ had also found claim 1 invalid and unenforceable due to inequitable conduct by Tanabe. See Pet. App. 124, 178-194. The Commission did not reach the invalidity and unenforceability issues given its rejection of Tanabe's infringement claim. *Id.* at 26.

guage, the specification, the prosecution history, and, as appropriate, extrinsic evidence. *Id.* at 13 (citing *Markman* v. *Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), aff'd, 116 S. Ct. 1384 (1996)). The court emphasized Tanabe's consistent references, in the claim, the specification, and the prosecution history, to "acetone" specifically, rather than to a broader category of "ketone solvents" that would include butanone as well as acetone. *Id.* at 13-14. The court also noted Tanabe's statements to the Patent and Trademark Office that the particular base/solvent combinations identified in claim 1 would produce higher yields than would existing processes. *Id.* at 14. The court concluded that such statements would suggest to "a person skilled in the art" that "substituting butanone for acetone is not an insubstantial change" in the process described in the '035 patent. *Id.* at 13-14.

The court then analyzed whether butanone is, in fact, the equivalent of acetone for purposes of the '035 patent. Pet. App. 14-18. The court noted that the substantial differences between butanone and acetone were demonstrated by the unsuccessful experiments with butanone by Fermion, Tanabe, and Tanabe's expert. *Id.* at 15-16. Fermion, for example, required more than two years of "extensive experimentation," using a variety of solvents, bases, and reaction conditions, before it could produce high yields of diltiazem using butanone. *Id.* at 18. The court also relied on Tanabe's statements to foreign patent offices that the particular base-solvent combinations specified in its patent applications were "not obvious" and produced substantially higher yields than did existing processes. *Id.* at 16. The court concluded that such evidence demonstrated that butanone is not readily

interchangeable with acetone in the claimed process, and thus that Tanabe did not have a valid infringement claim under the doctrine of equivalents. *Id.* at 16-18.

Finally, the court concluded that Tanabe's infringement claim also failed to satisfy the alternative "function-way-result" test for infringement under the doctrine of equivalents. Pet. App. 18. The court noted that the Commission had found that Tanabe's process "operates by way of a 'surface solid phase,'" whereas no such phase had been identified in Fermion's process. *Ibid.*

ARGUMENT

The decision below is fully consistent with this Court's holdings in *Warner-Jenkinson Co.* v. *Hilton Davis Chemical Co.*, 117 S. Ct. 1040 (1997), and its underlying concern that the doctrine of equivalents not be allowed to "enlarge the metes and bounds of the invention beyond what is claimed" in the patent. *Id.* at 1049 (internal quotation marks, italics, and citation omitted). The court of appeals construed the process claimed in the '035 patent as one with narrow "metes and bounds," as reflected in the language of the patent application and the prosecution history, and concluded that the accused process was not the equivalent of the patented process as so construed. The court's application of the doctrine of equivalents to the particular facts of this case does not warrant further review.

The court of appeals did not, as petitioners assert, create any new "estoppel," "counter-presumption," or exception to the doctrine of equivalents. Nor did the court, as petitioners further assert, rest its decision on the parties' subjective intent, in contravention of *Warner-Jenkinson*. Instead, the court simply took

into account all of the pertinent facts and circumstances in order to answer the two objective questions that must be resolved in any case under the doctrine of equivalents: first, how the patent at issue would be construed by "a person skilled in the art" and, second, whether such a person would have known of the alleged interchangeability of the claimed element and the accused element in the patented process or product. *Warner-Jenkinson*, 117 S. Ct. at 1052; *Markman* v. *Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), aff'd, 116 S. Ct. 1384 (1996).

This Court made clear in *Warner-Jenkinson* that further refinement of the doctrine of equivalents should be left, at least for the time being, to the Federal Circuit's "sound judgment in this area of its special expertise." 117 S. Ct. at 1054. No need exists for the Court to revisit the doctrine so soon after *Warner-Jenkinson*, especially in a case that does not purport to announce any new rules of general application, but merely to apply the established doctrine to particular facts.

1. In *Warner-Jenkinson*, the Court reaffirmed the doctrine of equivalents, as originally recognized in *Graver Tank & Manufacturing Co.* v. *Linde Air Products Co.*, 339 U.S. 605 (1950). The Court had made clear in *Graver Tank* that "[w]hat constitutes equivalency must be determined against the context of the patent," including "the purpose for which an ingredient is used in a patent, the qualities it has when combined with the other ingredients, and the function which it is intended to perform." 339 U.S. at 609. Yet, the Court expressed concern in *Warner-Jenkinson* that the doctrine of equivalents had, in the decades since *Graver Tank*, "taken on a life of

its own, unbounded by the patent claims"—in other words, that the doctrine was being applied so broadly as to "conflict[] with the definitional and public-notice functions of the statutory claiming requirement." 117 S. Ct. at 1048-1049. The Court therefore reiterated the primacy of the patent claim in each infringement inquiry, including those under the doctrine of equivalents, so that "the doctrine will not vitiate the central functions of the patent claims themselves." *Ibid.*

The opinion below comports with the fundamental teachings of *Warner-Jenkinson* and *Graver Tank*. The court properly began its analysis by ascertaining the precise scope and meaning of the '035 patent based on the claim language, the specification, and the prosecution history. See *Graver Tank*, 339 U.S. at 607 (in determining whether there is infringement under the doctrine of equivalents, "resort must be had in the first instance to the words of the claim"). The court found that Tanabe had narrowly defined its invention in terms of specific base/ solvent combinations. Pet. App. 13-14. The court further found that Tanabe had represented to the Patent and Trademark Office that those particular combinations produced significantly higher yields of diltiazem than did the existing processes. *Ibid.* The court concluded, on the basis of that evidence, that "a person skilled in the art" would construe the pertinent provision of the patent as encompassing only the acetone/potassium carbonate combination that was specifically identified, and not combinations of potassium carbonate with other ketone solvents. *Ibid.*

The court then turned to the second step of the equivalents inquiry: a comparison of the process claimed in Tanabe's '035 patent, as properly con-

strued, with the accused process used by Fermion. Consistent with *Warner-Jenkinson*, 117 S. Ct. at 1049, the court focused on the "individual elements of the claim," *i.e.*, the interchangeability of butanone for acetone in the process, rather than on "the invention as a whole." The court determined that butanone is not interchangeable with acetone in the process described in the '035 patent—a process that was said to produce particularly high yields of diltiazem—as reflected in extensive experiments conducted by Fermion, Tanabe, and Tanabe's expert demonstrating "that butanone generally produced substantially worse results." Pet. App. 17.

The court concluded, therefore, that Fermion had not infringed Tanabe's patent under the doctrine of equivalents. Nothing in the court's analysis suggests any tension with *Warner-Jenkinson*, which the court had an opportunity to consider before issuing its decision. See Pet. App. 12 (citing *Warner-Jenkinson*). Indeed, the court did not purport to articulate any new rule of general application with respect to the doctrine of equivalents, but instead simply applied the doctrine, as articulated in *Warner-Jenkinson* and similar cases, to the facts of this case.

2. Petitioners nonetheless contend (Pet. 9, 17) that the decision below conflicts with *Warner-Jenkinson* by creating "a new form of estoppel," or a "new limitation on the application of the doctrine" of equivalents, in addition to the prosecution history estoppel endorsed by this Court. See 117 S. Ct. at 1049-1051 (discussing prosecution history estoppel). That new "estoppel" or limitation" would supposedly preclude a patentee from claiming protection beyond the specific elements stated in its patent application, regardless of whether the patentee defined those elements nar-

rowly for reasons of patentability (as in prosecution history estoppel) or for unrelated reasons.

The Federal Circuit did not, however, purport to create any "new form of estoppel." To the contrary, the court expressly rejected petitioners' similar arguments that the International Trade Commission, in the decision under review, had improperly created new forms of estoppel based on pre-application experiments or on statements to foreign patent offices. See Pet. App. 15-16. The court merely held that the particular patent claim at issue here should be read narrowly in light of its express language and prosecution history. The court reasoned that Tanabe's reference to the specific chemical acetone, as opposed to the more general category of ketone solvents, would have caused "a person skilled in the art" to conclude that the patented process would work only with acetone. See *id.* at 13-17.

3. Petitioners next assert (Pet. 10, 17-18, 21) that the Federal Circuit improperly considered Tanabe's subjective intent for restricting its claim to acetone, in contravention of this Court's statement in *Warner-Jenkinson* that "intent plays no role in the application of the doctrine of equivalents." 117 S. Ct. at 1052. Contrary to petitioners' assertions, however, the court below did not consider why Tanabe specified acetone, but not butanone, in its patent claim; in fact, the court expressly refused to "speculate on Tanabe's reasons for disclosing and claiming the use of only one ketone solvent." Pet. App. 14. Instead, the court properly focused on the objective question of "how those skilled in the art would interpret certain language in the claim," based on the claim language, the specification, the prosecution history, and, as appropriate, extrinsic evidence. *Id.* at 13 (citing *Markman*,

52 F.3d at 979). It was, of course, relevant to that objective inquiry what terms Tanabe "chose" to use, and what terms Tanabe "could have used" but did not, in describing its invention to the Patent and Trademark Office. See *ibid.* (noting that Tanabe's "specific claim language would suggest to a person skilled in the art that ketones other than acetone may not be useful").[3]

4. Petitioners further contend (Pet. 10, 17-18 & n.11) that the decision below conflicts with *Warner-Jenkinson* by considering the state of knowledge about acetone and butanone at the time of patent issuance as well as at the time of infringement. But no such conflict exists. To be sure, *Warner-Jenkinson* states that, "[i]nsofar as the question under the doctrine of equivalents is whether an accused element is equivalent to a claimed element," the court's inquiry should focus on "the time of infringement." 117 S. Ct. at 1053. However, to the extent that the court below considered the state of knowledge about acetone and butanone at the time that the '035 patent was issued, the court was not doing so in the context of determining whether the two chemicals were equivalents. The court was instead addressing the analytically separate question of patent construction, which may

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[3] Petitioners also erroneously assert (Pet. 18) that the court relied on the subjective intent of Fermion, the alleged infringer, when it stated that Fermion's actions constituted "designing around" rather than "copying" the patent. In the passage cited by petitioners, however, the court used the phrase "designing around" simply to characterize the "extensive experimentation" required by Fermion to make the process work with butanone. Pet. App. 18. The court considered this experimentation to bear on the objective question whether butanone is interchangeable with acetone in that process. *Ibid.*

properly take into account the state of knowledge at the time that the patent was issued. See Pet. App. 13-15.[4]

5. Petitioners also argue (Pet. 10, 24-25) that the decision below "creates *as a matter of law* a counter-presumption" against application of the doctrine of equivalents in circumstances where "the interchangeability between an unclaimed and a claimed element becomes obvious." Again, however, petitioners are attempting to manufacture a general pronouncement of law out of a determination of fact specific to this case. Nothing in the opinion below purports to create any such legal "presumption." The court simply held, on the facts of this case, that petitioners had not met their burden of demonstrating that acetone and butanone are interchangeable for purposes of the process claimed in the '035 patent. Pet. App. 17-18.

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[4] Petitioners also argue (Pet. 10) that the court of appeals "compounded its error" by considering certain "non-public information," *e.g.*, records of experiments, that "became available only during litigation-related discovery." They assert (Pet. 22) that the reliance on such evidence is improper, because it undermines "the public notice function served by claiming." But the court did not consider this evidence in construing Tanabe's '035 patent claim, a question that implicates the "public notice function" of the statutory claiming requirement. The court considered the evidence only on the separate question of whether acetone and butanone are, in fact, equivalent. See Pet. App. 15. In any event, petitioners do not suggest that the court below articulated any rule of general application regarding such evidence, much less any rule that contravenes *Warner-Jenkinson* or any other decision of this Court. See *Warner-Jenkinson*, 117 S. Ct. at 1052 (recognizing relevance of evidence of alleged infringer's experiments to question of interchangeability).

6. Petitioners finally suggest (Pet. 27-29) that the Court should, at a minimum, grant the petition, vacate the judgment below, and remand the case to the Federal Circuit for reconsideration in light of *Warner-Jenkinson*. But such relief is not warranted here. The Federal Circuit panel was clearly aware of this Court's decision in *Warner-Jenkinson* when it issued its decision in this case. See Pet. App. 12 (citing *Warner-Jenkinson*). The full Federal Circuit subsequently denied petitioners' petition for rehearing, and suggestion of rehearing *en banc*, which expressly called *Warner-Jenkinson* to its attention. Pet. App. 20-21; Pet. 29 n.15. And, for the reasons discussed above, the Federal Circuit's decision is fully consistent with *Warner-Jenkinson*. In any event, given that the Federal Circuit also held that petitioners had failed to satisfy the alternative "function-way-result test for infringement under the doctrine of equivalents" (Pet. App. 18), any revision of the challenged aspects of the court's decision would not necessarily produce a different outcome in this case.[5]

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[5] Contrary to petitioners' suggestion (Pet. 29 n.15), the Court has no "longstanding practice" of granting, vacating, and remanding whenever (unlike in this case) the intervening decision was called to the lower court's attention only on a petition for rehearing. Rather, the Court has indicated that such relief is appropriate only when a "reasonable probability" exists that the intervening decision, if fully considered by the court below, would alter "the ultimate outcome of the litigation." *Lords Landing Village Condominium Council of Unit Owners* v. *Continental Ins. Co.*, 117 S. Ct. 1731, 1732 (1997). There is no reason to suppose that the Federal Circuit would, after even fuller consideration of *Warner-Jenkinson*, reach any different conclusion on petitioners' infringement claim.

This Court expressed its aversion in *Warner-Jenkinson* to "micro-managing" the further refinement of the doctrine of equivalents—a task that the Court concluded should be left to the Federal Circuit's "sound judgment in this area of its special expertise." 117 S. Ct. at 1054. Yet, petitioners are asking this Court to engage in precisely such "micro-managing" here. No reason exists for the Court to do so, either by reviewing the case on the merits or by remanding it to the court below.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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